UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCT LIABILITY LITIGATION

MDL No. 02419

Docket No. 1:13-md-2419-RWZ

This document relates only to:

Armetta, No. 1:14-cv-14022-RWZ
Bowman, No. 1:14-cv-14028-RWZ
Davis, No. 1:14-cv-14033-RWZ
Dreisch, et al. No. 1:14-cv-14029-RWZ
Farthing, No. 1:14-cv-14036-RWZ
Kashi, No. 1:14-cv-14026-RWZ
Torbeck, No. 1:14-cv-14023-RWZ
Handy No. 1:14-cv-14019-RWZ

PLAINTIFFS' BRIEF IN OPPOSITION TO BOX HILL DEFENDANTS' CONSOLIDATED MOTIONS FOR PARTIAL SUMMARY JUDGMENT

Patricia J. Kasputys, Esq. (*Pro Hac Vice*)
Jay D. Miller, Esq. (*Pro Hac Vice*)
Glenn E. Mintzer, Esq. (*Pro Hac Vice*)
Sharon L. Houston, Esq. (*Pro Hac Vice*)
Law Offices of Peter G. Angelos, P.C.
One Charles Center
Baltimore, MD 21201
410-649-2000 (Phone)
410-649-2101 (Fax)

Attorneys for Plaintiffs Armetta, Bowman, Davis, Dreisch, Farthing, Kashi, and Torbeck

Harry M. Roth, Esq. (*Pro Hac Vice*)
Michael Coren, Esq. (*Pro Hac Vice*)
Cohen, Placitella & Roth, P.C.
Two Commerce Square
2001 Market Street, Suite 2900
Philadelphia, PA 19103
215-567-3500 (Phone)
215-567-6019 (Fax)

Attorneys for Plaintiff Handy

Notice: During the September 21, 2017 MDL 2419 status hearing the Court granted Plaintiffs leave to file an enlarged page limit opposition brief of 30 pages to respond to the Box Hill Clinic Defendant movants' consolidated motion for summary judgment on seven claims listed in the motion and their seven separate memorandums in support of the motions. *See* Dkt. Nos. 3454, 3454-1, 3455, 3455-1, 3456, 3456-1, 3457, 3457-1, 3458, 3458-1, 3459, 3459-1, 3460, and 3460-1. The Court also extended the filing deadline for Plaintiffs opposition papers to October 16, 2017.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

I. INTRODUCTION

The Box Hill Defendants'[1] have filed motions for summary judgment which are based on the major premise that New England Compounding Pharmacy Inc.'s ("NECC's") compounding and dispensing vials of contaminated preservative-free methylprednisolone acetate ("MPA" or "MPA PF") is completely to blame and supersedes all other causes or responsibility for Plaintiffs' or Plaintiffs' decedents' injuries. The factual foundation for its premise, however, raises seminal questions: Why and how was NECC's contaminated preservative-free prescription compounded steroid preparation present in Maryland and being administered to Box Hill patients in the first place? Plaintiffs will prove that the only way NECC's contaminated product was administered to them or their loved ones was because of the failure of these defendants, and in particular Dr. Bhambhani, to meet the minimum standard of care regarding compounds, their production, and the rules and laws regarding their use. Thus, material questions are present for a jury to determine whether Box Hill's conduct and omissions proximately caused Plaintiffs' injuries and deaths. These are not displaced by NECC's conduct. Defendants' motions for summary judgment accordingly must be denied.

The medical profession long has known there were special risks in using compounding pharmacies to supply steroid medications used in epidural steroid injection ("ESI") procedures, such as MPA PF; a drug subjected to a very high-risk sterilization process.[2] In fact, the 2012 NECC

---

[1] Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (collectively "Box Hill Defendants," "Box Hill," or "Defendants").

[2] *See* Ex. 1 (MDL Deposition Exhibit No. 1365, *Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy*, Center for Disease Control – MMWR Weekly (December 13, 2012), Ex. 2 (MDL Deposition Ex. No. 1358, *The Special Risks of Pharmacy Compounding*, FDA – Consumer Health Information (May 31, 2007), Ex. 3 (March 8, 2017 Deposition of David Maine, M.D.) at 112:11-116:7; 254:5-259:1, Ex. 4 (March 22, 2016

MPA meningitis outbreak was not the first infection outbreak involving compounded MPA.[3] As a patient's learned intermediary, Dr. Bhambhani, to meet the standard of care under the law, had a duty to protect her patients throughout the treatment process which included evaluating the high-risk preservative-free MPA she prescribed and administered during ESI procedures. *Doe v. Miles Laboratories, Inc.*, 927 F.2d 187, 194 (4th Cir. 1991) (recognizing the learned intermediary doctrine); *see also Ames v. Apothecon*, 431 F. Supp. 2d 566 (D. Md. 2006) (same); *Gourdine v. Crews*, 177 Md. App. 471, 935 A.2d 1146 (2007), *aff'd* 405 Md. 722, 955 A.2d 769 (2008) (majority acknowledging existing line of authorities accepting the learned intermediary doctrine, but noting Maryland's Court of Appeals had not yet had occasion to consider adopting it; dissenting opinion noting the Court would and should recognize it); *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 821 (Mass. 2002) (acknowledging the learned intermediary doctrine in Massachusetts and declaring that "the physician is the appropriate person to perform the duty of warning a patient of the possible side effects of prescription drugs . . . .").

So, as alarming and despicable a jury may perhaps find the conduct of NECC, or NECC's head, Barry Cadden, that is not the beginning and the end of the story here. By no means. The fact remains—and as the record graphically shows—NECC's fungus contaminated MPA PF vials found their way to a rural Maryland outpatient clinic, hundreds of miles away from Massachusetts, and into the bodies of Box Hill's patients—to their grave harm—due to a doctor running an outpatient clinic who totally disregarded and failed to fulfill the professional responsibilities

---

Deposition of William Mixon) at 199:1-204:2; 334:4-338, Ex. 5 (August 4, 2016 Deposition of Lloyd Saberski, M.D.) at 89:8-90:9; 9413-95:3 (discussing compounded steroid outbreaks/recalls date to early 2000s).

[3] *Id.*

Maryland and Massachusetts laws impose upon them. Indeed, Dr. Bhambhani breached her solemn Hippocratic oath to "*first do no harm*" by outright violating statutes, regulations and medical standards of care on the prescription and administering of preservative-free compounded drugs designed and intended to protect her patients. It follows that what NECC (or anyone else named in these lawsuits) did or did not do does not supersede Box Hill's shortcomings and transgressions.

As discussed more particularly below, the record herein permits the Box Hill Defendants to be found liable at trial on many bases. Their triable negligence includes: (1) mail-ordering hundreds of vials of prescription preservative-free MPA from NECC without making any reasonable effort to assess and evaluate NECC's ability to aseptically make, package, and dispense preservative-free MPA, which is a difficult and very high-risk preparation to make; (2) ordering compounded MPA PF from NECC without a valid medical reason relating to a specific Plaintiff patient's medical need for a compounded drug, instead of using available manufactured ones from a Food & Drug Administration ("FDA") regulated manufacturer like Pfizer; (3) ordering what were single patient vials of MPA PF in 5ml size vials and then using these single use vials for multiple patients;[4] and (4) ordering MPA PF from NECC using names of previous patients from

[4] The distinction between a single use vial and a multiple use vial is that multiple use vials contain volumes of medicine that can provide a therapeutic dose to more than one patient *and* contain a preservative agent to prevent infection. *See e.g.,* Ex. 6 (March 1, 2017 Deposition of Steven Cohen, M.D.) at 150:4-20. Box Hill's practice of using medication from single use vials on multiple patients for ESIs violated both Center for Disease Control ("CDC") guidelines on single use vials, as well as Box Hill's own internal aseptic practices guidelines which adopt the CDC's guidelines. *See* Ex. 7 (February 2, 2017 Deposition of Dennis Killian, PhD.) at 150:6-151:19. According to Plaintiffs' expert Shmuel Shoham, M.D., Box Hill's use of single use vials on multiple patients violated applicable standards of care. Ex. 8 (January 19, 2017 Deposition of Shmuel Shoham, M.D.) at 105:20-106:2.

treatment schedules, including names of patients who had not been scheduled for a MPA injection, and then administering the contaminated steroids dispensed in those patients' names to different patients, including Plaintiffs. In so doing, Box Hill Defendants violated Massachusetts and Maryland law, and exposed patients like Plaintiffs to an unnecessary foreseeable high risk of serious personal injury and death. Their negligence and recklessness caused Plaintiffs to receive contaminated MPA PF injections, and consequently sustain serious personal injury and, in some cases, suffer death.

II. ARGUMENT

A. Because disputed material facts exist, the Box Hill Defendants fail to meet their burden of proving summary judgment should be entered in their favor regarding their breach of a duty owed to Plaintiffs.

To succeed in a medical negligence claim under Maryland law, a plaintiff must show, among other things, the existence of a duty of care owed. *See Sterling v. Johns Hopkins Hosp.*, 145 Md. App. 161, 169, 802 A.2d 440, 445 (2002). "The duty of care owed to an individual in the medical context is based primarily on the *existence of the physician-patient relationship*." *Id.* (emphasis added). Instantly, it is undisputed that the infected Plaintiffs and Box Hill Defendants were in a physician-patient relationship at the time Dr. Bhambhani injected Plaintiffs or their loved ones with contaminated MPA. Pursuant to this relationship, the Box Hill Defendants clearly owed Plaintiffs a duty of care. As Plaintiffs' experts will testify, that duty requires a doctor to understand the issues regarding the safety and efficacy of medications she is providing to her patients and to use reasonable care to assure patient safety. *See* Ex. 9 (September 11, 2016 Expert Report of Lloyd Saberski, M.D.), Ex. 10 (September 14, 2016 Expert Report of Shmuel Shoham, M.D.), Ex. 11 (July 13, 2016 Expert Report of Mr. David Chason).

Box Hill Defendants' motions ignore this fundamental tort law in claiming no such duty to Plaintiffs exists because there is no recognized "due diligence" duty. *See* Dkt. Nos. 3456-1 at 7-8, 3457-1 at 8-11. Box Hill's semantic manipulation of Plaintiffs' position is inadequate to construct a legitimate question of law for the Court to decide. The existence of the duty of a physician to exercise reasonable care, indeed to serve as a patient's *learned intermediary*, in selecting injectable steroids for her patients cannot seriously be questioned. Box Hill's makeweight argument is no more than an attempt to avoid the ultimate issue—whether a duty was *breached*, not owed. Indeed, a defendant's breach of duty is a question of fact for the jury, and Box Hill's request for partial summary judgment should be denied on this basis alone. *See Sterling*, 145 Md. App. at 169, 802 A.2d at 445 (observing that breach of duty is generally a question of fact, not law).

In seeking summary judgment Defendants mischaracterize Plaintiffs' framing of the applicable duty owed. Dkt. No. 3456-1 at 8-11. Plaintiffs will prove that, consistent with Maryland law, the duty owed is the degree of care and skill that would be used by a reasonably competent health care provider engaged in a similar practice and acting in similar circumstances. *See Powell v. Breslin*, 195 Md. App. 340, 347, 6 A.3d 360, 364 (2010); *see also McQuitty v. Spangler*, 410 Md. 1, 19, 976 A.2d 1020, 1031 (2009) (discussing whether defendant physician "breached a duty to exercise ordinary medical care and skill based upon the standard of care in the profession."). Further, the duty owed is subject to a national standard of care that is derived through uniform requirements for certification, accreditation, postgraduate training, modern communications, medical literature, seminars, conferences and other developments in the medical profession. *See generally Shilkret v. Annapolis Emergency Hospital Association*, 276 Md. 187, 349 A. 2d 245 (1975). With this standard in mind, Plaintiffs' experts, in their reports and deposition testimony,

each opined that Dr. Bhambhani's conduct was unreasonable in these cases for a number of reasons they are competent to opine upon, including in summary form:

a. While Dr. Bhambhani's professed explanation for why she used NECC's MPA PF was a belief preservative-free MPA was safer for her patients, NECC's compounded MPA PF (which was her only known source of it) contained the preservative polyethylene glycol ("PEG"). PEG happens to be the preservative associated in the medical literature with adverse patient reactions to ESI steroids.[5] Thus using NECC's MPA exposed her patients to the very risks of preservatives in steroids she claimed to be concerned about and wanted to avoid, and further exposed her patients to an increased risk of contamination and ineffective medications by using a compounding pharmacy as the source of MPA PF instead of purchasing a FDA approved manufacturers' version through normal supply channels, which was available had she bothered to look;

b. After an alleged conversation with a doctor colleague about steroids led her to a belief that MPA PF was safer for her patients than what she had been using (and was taught during her training), Dr. Bhambhani did no independent literature research to confirm that MPA PF was safer than preservative formulations or other steroids. Nor did she do any investigation into the risks of contamination and inconsistent formulation of mass compounded drugs when compared to those manufactured by FDA overseen suppliers.

[5] As Dr. Saberski explains in his expert report: "The MPA product made by NECC and presumed to be preservative-free was actually only benzyl alcohol-free. It however contained other preservatives, including polyethylene glycol (PEG), which had been widely implicated as a cause of arachnoiditis when injected into the sub-arachnoid space. Thus, every one of the patients injected by Dr. Bhambhani at the Box Hill Surgery Center received MPA containing PEG; the product injected was not truly preservative-free." Ex. 9 at 3; s*ee also* Ex. 5 at 105:15-107:1

Had she looked on the internet, for example, she would have readily learned the peculiar risks associated in using compounded MPA PF from easily found articles such as FDA published;[6]

c. Because she was unaware of the risks, Dr. Bhambhani never advised her patients of the risks and alternatives to the compounded formulas she was injecting; and

d. Dr. Bhambhani used large sized (5ml) "single use" vials of compounded MPA to inject into multiple patients and to obtain these MPA PF vials she wrote bogus prescriptions Box Hill faxed to NECC.

In support of Plaintiffs' claim that Box Hill Defendants breached a duty to exercise ordinary and reasonable medical care in accordance with the legal standard of care, Plaintiffs offer the expert report and testimony of Lloyd R. Saberski, M.D., a pain management specialist practitioner. Dr. Saberski opines that "the standard of care requires that any injectable substance a physician administers be safe, sterile, and prepared to accepted industry standard." Ex. 9 at 2. Dr. Saberski concludes that Box Hill violated this standard by: (1) purchasing and administering NECC's compounded MPA when there were FDA approved benzyl alcohol-free deposit steroids available; (2) failing to comply with applicable Massachusetts and Maryland statutes, regulations, or guidelines governing the prescription and dispensing of compounded prescription medication for patients (they require patient specific prescriptions);[7] (3) neglecting to inform patients that

[6] *See* Ex. 2.

[7] It was not difficult for an out-of-state doctor to learn what Massachusetts' prescription laws and standard of care required. Massachusetts' Board of Registration in Medicine, since 1989, published a resource on these subjects which was available (even on-line) when Dr. Bhambhani decided to use an out-of-state Massachusetts' pharmacy as her MPA source. *See* Ex. 12 (March 10, 2017 Deposition of Thomas Larkin, M.D.) at 226:20-229:4 (discussing Ex. 13 (MDL Deposition Exhibit

NECC's MPA was a compounded and not a FDA approved manufactured steroid; and (4) negligently administering MPA from 5ml single use benzyl alcohol preservative-free vials to multiple patients rather than drawing from individual single-dose vials. *See* Ex. 9 at 4-5, Ex. 14 (January 12, 2017 Deposition of Lloyd Saberksi, M.D.) at 85:10-90:15; 107:16-111:21; 132:13-133:14; 134:9-13; 136:9-137:22; 147:22-150:7; 153:2-154:2; 190:1-20. He further expresses an opinion that Box Hill's lack of due diligence when dealing with a compounding pharmacy violated the standard of care. *Id*. at 56:8-20, 103:14-104:12, 147:22-148:11, 153:3-13.

Despite Plaintiffs' expert opinions, Box Hill Defendants claim entitlement to summary judgment because Dr. Bhambhani acted the same as other doctors and clinics. Dkt. No. 3456-1 at 10-11. Here, Box Hill is plainly wrong as those physicians also clearly violated the standard of care. Ex. 14 at 133:15-21; 135:3-136:1; 154:3-155:4. Furthermore, Box Hill's reliance on industry custom is unsupported by admissible data. What other doctors did is of no moment since, by her own admission, Dr. Bhambhani neither knew nor relied upon what other doctors across the United States did regarding the ordering and use of NECC's MPA. Ex. 15 (February 10, 2016 Deposition of Ritu Bhambhani, M.D.) at 99:23-100:11. What is more, these referenced, unspecified doctors' practices violated the law (Ex. 14 at 134:9-135:18),[8] and evidence of an industry or other custom

---

1627-14, Prescribing Practices, Policy and Guidelines, adopted August 1, 1989, and amended November 17, 2010)).

[8] In ordering and dispensing MPA from NECC, Box Hill Defendants were required to comply with the Code of Maryland Regulations ("COMAR") and the Massachusetts state law that governed pharmaceutical compounding and dispensing activities as an out-of-state licensed prescriber. *See* Ex. 16 (Dreisch Complaint) at ¶¶ 117, 155-157, 227. Plaintiffs will ask the Court to take judicial notice of the relevant statutes and regulations, and will offer additional evidence at trial to show how the Box Hill Defendants failed to adhere to both Maryland and Massachusetts law, as well as American Society of Health-System Pharmacy Guidelines on Outsourcing Sterile Compounding Services Guidelines, to protect the safety of patients who received MPA injections, and how the

repugnant to a governing statute is typically excluded.[9] But, even were this evidence of industry custom admissible, it ignores the proper question before the Court and jury about whether Dr. Bhambhani's conduct was *reasonable*.

Plaintiffs also offer the expert report and testimony of Mr. Chason, a pharmacist. He opines that Dr. Bhambhani's writing non-patient-specific MPA prescriptions, ignorance of governing

---

failure to do so caused Plaintiffs' injury. As it is the State of the drug's dispensing, Massachusetts' pharmacy laws apply pursuant to Massachusetts controlled substances statute, which governs all prescription medications. Mass. Gen. Laws Ch. 94C, § 18(c) ("A prescription . . . may also be issued by an authorized practitioner who is duly licensed to practice medicine and duly registered in the state wherein he resides, if required, and duly registered under federal law to write prescriptions . . . . Any prescription issued under this paragraph shall be issued in the manner prescribed in section twenty-two and all relevant provisions of this chapter shall apply to such physician and prescription.").

[9] *See Republican Pub. Co. v. Am. Newspaper Guild*, 172 F.2d 943, 946 (1st Cir. 1949) (Fair Labor Standard Act case concerning the appropriate calculation of work hours, and rejecting the newspaper industry's customary calculation stating, "the statute overrides any custom or understanding to the contrary."); *McGuire v. Amrein*, 101 F. Supp. 414, 419 (D. Md. 1951) ("[I]t may be said in general that the law is clear enough that one may not establish a custom contrary to law . . . ."); *Alley v. Siepman*, 214 N.W.2d 7, 11 (S.D. 1974) (noting that, "evidence is not admissible to show a custom which is in conflict with a statute or ordinance," and that "[a]bsent a recognized legal excuse, the violator is held to the standard fixed by the statute. We do not regard the showing of a custom or practice of violating the law as a legal excuse not to follow the law."); *Sanchez v. J. Barron Rice, Inc*., 427 P.2d 240, 243, 245 (N.M. 1967) ("[E]vidence is not admissible to show a custom in conflict with the standard imposed by statute or ordinance."); *Wood v. Melton*, 293 P.2d 252, 255 (Kan. 1956) (affirming trial court's decision to preclude a defense based on custom when the custom violated law, noting that "the alleged custom, practice, and usage which is contrary to existing law cannot be used either to establish or defeat an action and evidence thereof cannot be received."); *Langner v. Caviness*, 28 N.W.2d 421, 424 (Iowa 1947) ("It is generally held, however, that a custom which conflicts with a statutory provision will not be enforced. Where there is such conflict, the statute must control."); *Bd. of Educ. v. Howard Cty*., 413 A.2d 568, 575 (Md. App. 1980) ("[T]he requirements of statutes cannot be avoided by custom or private understandings to the contrary.").

regulations concerning prescription writing, failure to research compound manufactured products, and improper use of single-use vials on multiple patients, along with the Box Hill Defendants' deficient pharmaceutical policies and procedures, limited vendor review processes, inadequate storage and refrigeration practices, and avoidable errors in record keeping, were problematic and sub-par. Ex. 17 (December 21, 2016 Deposition of David Chason) at 157:19-25; 163:10-165:4; 175:20-177:9; 193:4-16; 201:7-202:7; 207:7-208:8; 210:4-211:10; 221:10-222:1; 222:11-223:14; *see generally* Ex. 11.

Plaintiffs further submit the expert report and testimony of Dr. Shoham, a board certified internal medicine and infectious disease doctor. Dr. Shoham opines that the Box Hill Defendants' non-patient specific and single vial, multi-dose MPA PF purchasing and administration practices violated not only the standard of care, but also Maryland law, and that the distribution and application of NECC's contaminated MPA caused patients in Maryland to suffer significant injuries and death. Ex. 10; *see also* Ex. 8 at 42:11-43:18; 56:25-57:10; 108:6-109:9.

Dr. Saberski's, Mr. Chason's, and Dr. Shoham's expert reports and testimony are sufficient to defeat Box Hill's request for partial summary judgment. This evidence, when viewed in the light most favorable to the Plaintiffs, provides a juror sufficient proof to reasonably conclude that Box Hill Defendants failed to exercise ordinary medical care to prevent the injection of contaminated MPA into Plaintiffs. *See Yerardi v. Pac. Indem. Co.*, 436 F. Supp. 2d 223, 237 (D. Mass. 2006) ("A genuine issue is one that must be decided at trial because the evidence, viewed in the light most flattering to the non-movant would permit a rational fact finder to resolve the issue in favor of either party.") (internal quotations and citations omitted).

Box Hill's request for partial summary judgment should also be denied because Dr. Saberski's, Mr. Chason's, and Dr. Shoham's conclusions directly conflict with the Box Hill

Defendants' experts' opinions that Box Hill complied with the standard of care. *Compare* Exs. 9, 10, and 11 *with* Dkt. No. 3456-1 at 8. These contradicting opinions create issues of material fact to be decided by a jury. *See Pichowicz v. Atl. Richfield*, Civil No. 92-388-M, 1997 U.S. Dist. LEXIS 23975, at *3 (D.N.H. Nov. 21, 1997) ("Expert witness opinions may create a genuine dispute as to a material fact sufficient to avoid summary judgment if the opinion is not merely conclusory but instead includes 'the factual basis and the process of reasoning which makes the conclusion viable.'") (quoting *Hayes v. Douglas Dynamics, Inc*., 8 F.3d 88, 93 (1st Cir. 1993)); *see also Nieto-Vincenty v. Valledor*, 22 F. Supp. 3d 153, 160 (D.P.R. 2014).

Box Hill attempts to discredit Plaintiffs' experts' opinions as unreliable aberrations. Dkt. No. 3456-1 at 11. Their conclusory position not only lacks any evidentiary foundation but also gives proof why summary judgment is inappropriate. "At summary judgment . . . courts normally assume that the trier of fact would credit the expert testimony proffered by the non-movant." *Den Norske Bank AS v. First Nat'l Bank of Boston*, 75 F.3d 49, 58 (1st Cir. 1996). Box Hill presents no evidence challenging the foundation of Dr. Saberski's, Mr. Chason's, or Dr. Shoham's expert reports or testimony that should cause the Court to depart from this practice.

Ultimately, it was the Box Hill Defendants who were in the best position to protect Plaintiffs who entrusted Box Hill for medical care. As Plaintiffs' learned intermediaries Defendants had a duty to provide reasonable medical care. This standard imposes the obligation on them to know whether the medications Dr. Bhambhani injected into her patients' spines were regulated by the FDA; whether the MPA supplier was reputable and competent; and what safety measures needed to be taken to ensure the sterility and safe administration of MPA PF to Plaintiffs. For years, Box Hill Defendants were negligent in not properly vetting NECC, ordering and prescribing preservative-free MPA, and not following specific patient prescription regulations and

distributing MPA to multiple patients from single use multi-dose vials. It is of absolutely no legal moment that before the 2012 fungal meningitis outbreak Dr. Bhambhani and Box Hill were fortunate enough to not experience and realize the grave risks they exposed their patients to in using NECC's MPA PF. Plaintiffs have clearly set forth facts and offered expert opinion supporting allegations of Box Hill Defendants' duty and breach of the applicable standard of care warranting denial of the motion for partial summary judgment. *See* Dkt. Nos. 3456, 3457.

B. Box Hill Defendants' negligence can be found to have caused Plaintiffs' injuries thereby precluding summary judgment in Defendants' favor.

Plaintiffs will prove that the negligence of Box Hill Defendants resulted in the acquisition of the tainted injectable steroids Dr. Bhambhani used and injected into her patients, causing them fatal and severe injuries. Box Hill's and Dr. Bhambhani's argument that they did not proximately cause Plaintiffs' injuries is both factually and legally wrong. *See* Dkt. Nos. 3455-1 at 7-11; 3457-1 at 11-13. They simply miss the point, or purposely misrepresent the causation issue for the Court and jury, when they contend that even if they would have exercised "due diligence" or issued "patient specific prescriptions" Plaintiffs' injuries still would have occurred because NECC distributed contaminated MPA. *Id*.

NECC's misconduct is clear in this case, but for purposes of this motion quite beside the point. Plaintiffs will prove that the harm to the Box Hill patients would have been *avoided* had Dr. Bhambhani complied with the minimum standards of care regarding a physician's attendance to the safety and efficacy risks of using a mass compounded steroid. In short, had Dr. Bhambhani had the requisite knowledge she should have, and/or exercised the diligence required by the minimum standard of care, there are several reasons why she never would have considered acquiring MPA PF from a mass compounder like NECC. Dr. Bhambhani really had no more familiarity with NECC than its fax number and what was on their Federal Expressed vials. As

discussed above, Plaintiffs will prove that the standard of care required that a physician using injectable steroids know that mass compounding increased the risk of contaminated product when compared to FDA manufacturers. Dr. Bhambhani, however, had zero knowledge of this risk and did nothing to educate herself about the risks and benefits of suppliers of medications for her patients. Dr. Bhambhani' s negligence in this regard increased the risk and likelihood of exactly what happened here, that she would inject her patients with an improperly made dangerous compound. Summary judgment is wholly unwarranted.

Under Maryland law a plaintiff must show the defendant's negligence was the proximate cause of the injury to make out a successful claim. *See Pittway Corp. v. Collins*, 409 Md. 218, 243, 973 A.2d 771, 786 (2009). "To be a proximate cause for an injury, the negligence must be 1) a cause in fact, and 2) a legally cognizable cause." *Id.* (internal quotations and citations omitted). "Causation-in-fact concerns the threshold inquiry of whether defendant's conduct actually produced an injury." *Id.* Legal cause referred to hinges on "a determination of whether the injury was foreseeable." *Wankel v. A&B Contractors, Inc.*, 127 Md. App. 128, 158, 732 A.2d 333, 349 (1999) (internal quotations and citations omitted).

Proximate cause analysis is reserved for the trier of fact unless the issue of causation is so clear that reasonable minds could not differ. *Pittway Corp.*, 409 Md. at 253, 973 A.2d at 792; *see also Collins v. Gui-Fu Li*, 933 A.2d 528, 549 (Md. App. 2007) (observing that proximate cause is a jury question unless the facts are undisputed and susceptible of but one inference). It is well accepted that expert reports and deposition testimony may provide sufficient evidence to create an issue of material fact as to the question of causation, prohibiting summary judgment in favor of the moving party. *See, e.g., Morales v. Monagas*, 723 F. Supp. 2d 411, 415 (D.P.R. 2010). The

evidence here, namely Plaintiffs' experts' reports and testimony, demonstrate that a reasonable juror could resolve the causation issue in Plaintiffs' favor.

As set out above, Plaintiffs' experts concluded that Box Hill committed multiple breaches of the applicable standard of care. Plaintiffs' experts further opine that Plaintiffs' injuries were the result of those numerous breaches. Ex. 9 at 5, Ex. 11 at 2, Ex. 14 at 66:16-20, Ex. 17 at 229:24-230:8. Dr. Saberski made clear that Dr. Bhambhani had no real reason to call for a compounded drug and therefore never should have purchased MPA from a compounding pharmacy in the first place. Ex. 14 at 78:3-81:1; 86:5-89:3; 99:3-15; 121:19-122:9. Thus, Plaintiffs satisfy the cause-in-fact requirement because but-for Dr. Bhambhani's negligent purchase and prescription of NECC MPA, Plaintiffs would not have been exposed to and injured by NECC's contaminated steroid.

With regard to legal cause, ironically, Plaintiffs' injuries were foreseeable for the same reasons Box Hill claims its conduct was not the cause. *See* Dkt. Nos. 3455-1 at 7-11; 3457-1 at 11-13. Had Dr. Bhambhani exercised due diligence in ordering MPA—which the red flags of being asked to submit bogus prescriptions should have strongly suggested was needed—she would have known that NECC MPA was at a high risk for contamination. Ex. 14 at 56:12-20; 79:13-80:5; 96:22-97:14; 102:11-103:10; 170:18-171:19, Ex. 17 at 175:20-177:9; 178:19-179:1. Box Hill Defendants would have also discovered NECC's unsuitable, checkered history, including prior reprimands, problems and complaints related to its practices and products, as well as a history of FDA and Massachusetts regulatory agency violations, including:

1. An April 1999 Massachusetts Board of Registration in Pharmacy complaint resulted in an Informal Reprimand letter based on NECC's violation of state law by including blank prescriptions in solicitations to doctors. Ex. 18;

2. Adverse events reported via MedWatch complaints to the FDA in 2002 concerned two patients who contracted meningitis and the suspected source of infection was NECC MPA PF.

Ex. 19 at 4. A subsequent FDA investigation revealed 5 of 16 vials were contaminated with bacteria. *Id.*, at 5-6 (BORP0016797-98); *see also* Ex. 20 (FDA Report on NECC Complaints and Inspections);

3. By letter dated October 4, 2004, the Massachusetts Department of Public Health offered NECC a Consent Agreement with a reprimand and a three year probation period for failure to comply with accepted standards in compounding a certain order of MPA PF. Ex. 21;[10]

4. A December 2006 FDA warning letter addressed to NECC detailing numerous problems concerning the sale of compounded drugs without patient specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. Ex. 24; and

5. On April 15, 2011, the Colorado Board of Pharmacy ordered NECC to cease and desist the distribution of non-patient specific compounded drugs to Denver hospitals. Ex. 25.[11]

Further, Dr. Bhambhani and Box Hill should have known a doctor may not legally administer medication prescribed and dispensed for one patient to another patient; that it was wrong for a doctor to prescribe a compounded medication without medical reason for a specific patient's specific medical needs; and administering numerous doses of a preservative free sterile preparation to different patients drawn from the same "single use" vial was not proper. Ex. 14 at 109:13-111:21; 112:9-113:20; 118:3-13. Box Hill's utilization of unacceptable (and illegal) purchasing and administration practices all contributed to Plaintiffs' injures, as but for them, the NECC's MPA PF would not have been present in Maryland and utilized as it was. That for several years Bhambhani (and other practitioners) used NECC MPA PF without incident does not absolve

[10] NECC did not consent to this proposed agreement (*see* Ex. 22), and, ultimately, the Board and NECC agreed to a one-year probation period with respect to complaints arising out of an adverse event complaint regarding MPA PF and dispensing Tryptan Blue without a valid prescription. Ex. 23.

[11] All of these documents were readily available to the public and easily discoverable at the time Box Hill Defendants purchased MPA from NECC.

her, other Box Hill Defendants, or anyone else from doing what they reasonably should have known not to do and have done. Ex. 14 at 118:15-20. Box Hill should have also known that its unsatisfactory methods of storage of the multi-dose NECC MPA vials could accelerate fungal and bacteria growth, thus making contaminate parts per vial more significant. Ex. 17 at 207:7-208:8. The evidence therefore demonstrates that Plaintiffs' injuries were foreseeable, and legal cause is met.

At both the beginning and end of the Plaintiffs' saga is the fact that it was the Box Hill Defendants who brought NECC's MPA into Maryland through illegal prescriptions and negligent medical practice. It was the Box Hill parties who were the last to handle the NECC contaminated MPA when it was administered to Plaintiffs. Each Plaintiff or their decedent was given contaminated MPA at the Box Hill clinic that had been prescribed and dispensed for another patient and without any requisite determination the patient actually needed a compounded versus a manufactured preparation. None were told what they were getting, why they were getting it, and the risks involved. Had Box Hill, as Plaintiffs' learned intermediaries, appropriately researched MPA PF and its risks and then appropriately vetted NECC, they would have known NECC was a compounding pharmacy acting as an unregulated manufacturer, one which was compounding purportedly sterile drugs in deplorable conditions, and one which was dispensing medications in violation of law. Red flags in this matter abounded but were ignored by Dr. Bhambhani and Box Hill. Under the facts here, Dr. Bhambhani and Box Hill's breaches of professional standards of care and violations of Massachusetts and Maryland prescription laws can clearly be found to have contributed to and resulted in the Plaintiffs' injuries. Plaintiffs accordingly proffer sufficient evidence demonstrating how Box Hill's negligent conduct was thus a proximate cause of the

Plaintiffs' injuries. Box Hill's request for partial summary judgment on this issue should therefore be denied. *See* Dkt. Nos. 3455, 3457.

C. NECC's conduct is not a superseding cause and does not relieve Box Hill Defendants of liability to Plaintiffs.

Box Hill Defendants assert that NECC's conduct (including that of its chief employee, Barry Cadden) intervened between its negligence and Plaintiffs' injuries from the administration of the contaminated MPA injections, thereby superseding (terminating) Box Hill's liability. *See* Dkt. No. 3454-1. This is incorrect as a matter of law because NECC's misconduct was reasonably foreseeable from both: (1) the significant patient safety risks attendant to acquiring on blind faith high-risk compounded sterile steroid medication for spine injections by mail order from an out-of-state compounding pharmacy instead of through normal medicine supply channels from a FDA licensed and inspected manufacturer; and (2) Box Hill's aiding and abetting NECC's flaunting drug prescription laws designed to protect patients, thereby subjecting Box Hill patients to increased risk of a contamination or other medication mishap. Furthermore, notably, Barry Cadden was acquitted of the homicide charges relating to the Maryland victims, including Box Hill's patients.

Maryland law provides that "[t]he chain of causation may be broken by an intervening force (negligent or non-negligent) that may, in turn, become a superseding cause, in which case the original tortfeasor's liability will terminate." *Yonce v. Smithkline Beecham*, 111 Md. App. 124, 140, 680 A.2d 569, 576 (1996). *Yonce* explains superseding cause as:

> When more than one act of negligence arguably could be responsible for the injury, the question that is presented is whether the second in point of time superseded the first, *i.e.*, did that act intervene and supersede the original act of negligence, thus terminating its role in the causation chain?

*Id. (*quoting *Hartford Ins. Co. v. Manor Inn*, 335 Md. 135, 157, 642 A.2d 219, 230 (1994)). The *Hartford* decision further explains that "[a]n intervening force is a superseding cause if the intervening force was not foreseeable at the time of the primary negligence." *Hartford Ins. Co.*, 335 Md. at 157, 642 A.2d at 230. Thus, a Maryland law superseding cause analysis focuses on *both* the foreseeability of harm suffered by the plaintiff and the foreseeability of the alleged intervening acts. *Pittway Corp.*, 409 Md. at 253, 973 A.2d at 792. Like issues of proximate causation, issues concerning superseding cause are questions for the trier of fact and only become a question of law if "the evidence presented and all the logical inferences deducible therefrom admit but one conclusion." *Collins*, 176 Md. App. at 537, 933 A.2d at 549.

Here, a reasonable juror could analyze Plaintiffs' evidence and logically infer that NECC's conduct was not a superseding cause exonerating Box Hill Defendants from liability, but rather a predicate fact supporting Box Hill's own liability. As discussed in preceding sections, Plaintiffs' injuries were reasonably foreseeable to the Box Hill Defendants. For the same reasons, NECC's inability to reliably produce sterile MPA safely was also reasonably foreseeable. Had Dr. Bhambhani and the Box Hill Defendants exercised any due diligence in acquiring office supplies of MPA from NECC—especially after being asked by NECC to submit bogus prescriptions to obtain it—they would have uncovered numerous other reasons (in addition to being asked to violate drug laws) why it should have gone elsewhere, including the deplorable conditions in NECC's compounding clean room Box Hill now ironically wants to parade before a jury. It also would have led to them better appreciate the consequential heightened risks in using NECC compounded pharmaceuticals it was exposing its patients to.

Contrary to Box Hill Defendants' contention, NECC's drug compounding errors were not unusual or extraordinary. *See* Dkt. No. 3454-1 at 11-12. Dr. Bhambhani was of course unaware of

any issues concerning NECC's compounding operations, or compounding pharmacies in general because, despite her professional obligation, she never looked, into, read about or otherwise investigated preservative-free steroid drug issues or using a compounded versus manufactured sterile injectable drug. She just did not bother or care. Had she looked, Dr. Bhambhani would have discovered several indicia of NECC's and other compounding pharmacies' malfeasance over the past years showing what happened in 2012 was not unpredictable. *See* Ex. 14 at 56:12-20; 79:13-80:5; 96:22-97:14; 102:11-103:10; 170:18-171:19, Ex. 17 at 175:20-177:9; 178:19-179:1, Ex. 18, Ex. 19, Ex. 20, Ex. 21, Ex. 24, and Ex. 25.

Box Hill's attempt here to avoid liability on the back of Barry Cadden's criminal convictions also fails. *See* Dkt. No. 3454-1 at 12-15. While Defendants are correct Mr. Cadden was convicted in this Court on March 22, 2017 of racketeering and mail fraud in connection with the 2012 nationwide fungal meningitis outbreak, they are gravely mistaken that these convictions are a superseding cause of Plaintiffs' injuries. First, he was not convicted of committing any homicides he was charged with. Second, and more importantly, his criminal misbehavior is completely beside the point as it does not displace the litigation's central proximate cause issue—how was it the contaminated MPA ended up in Box Hill patients' bodies? The answer to this question lies in what the Box Hill Defendants did and did not do. As Plaintiffs' experts opine, Plaintiffs were infected by the contaminated MPA due to Dr. Bhambhani's failure to satisfy the standard of care in selecting, purchasing, prescribing, and administering preservative-free MPA from an out-of-state compounding pharmacy it had no real basis to trust. Mr. Cadden's criminal conduct has no bearing on Dr. Bhambhani's negligent conduct, and that is simply an incidental predicate fact leading to Box Hill's liability.

Box Hill Defendants also ignore the fact it was they who created an opportunity for Mr. Cadden to commit criminal acts and that he was likely to do so when Box Hill Defendants, in confederation and concert with NECC, broke the law by purchasing preservative-free MPA through bogus, non-specific patient prescriptions. *See Valentine v. On Target, Inc.*, 353 Md. 544, 566, 727 A.2d 947, 958 (1999) (quoting Restatement (Second) of Torts § 448 (1979) and observing that a third party's criminal conduct is foreseeable and thus not a superseding cause when a defendant provides the third party an opportunity for such criminal conduct). Box Hill Defendants' professed ignorance of the applicable statutory and regulatory controls fostered and permitted NECC's and Mr. Cadden's unbridled compounding and distribution practices to flourish, permitting them to mass produce high risk sterile preparation for huge profits. *See* Ex. 14 at 107:16-110:20. The dangerous risk for contamination in preservative-free compounded pharmaceuticals is the very reason why the law requires patient-specific prescriptions. *Id*. at 182:13-183:14. Box Hill Defendants speciously claim Mr. Cadden's criminal conduct was unforeseeable because NECC's compounding facility passed an inspection a week prior to the first batch of contaminated MPA being recalled in May 2012. Dkt. No. 3454-1. This evidence carries little weight. Box Hill Defendants conveniently omitted the fact that the inspecting agency failed to examine the NECC compounding clean room—the MPA vial contamination location. Ex. 14 at 146:7-15, Ex. 26 (June 4, 2015 Deposition of Michael) at 83:12-84:23; 166:7-167:2; 173:22-174:4; 178:1-9; 181:19-183:17; 191:12-192:10; 193:10-197:13; 219:13-220:12, Ex. 27 (June 3, 2015 Deposition of Francis McAteer) at 190:9-17; 199:15-200:20; 201:17-203:12; 221:22-222:11; 227:8-14; 267:15-19. How they missed the recycling facility in NECC's backyard during their inspection is also mystifying. It also was inconsistent with what FDA and other investigators found when they examined NECC's facility following the MPA recall in 2012.

In short, partial summary judgment on this issue is inappropriate because the evidence here allows a reasonable juror to conclude that NECC's and Mr. Cadden's conduct are not superseding causes relieving Box Hill Defendants of liability. The inherent risks in using a compound pharmacy to prepare and dispense very high risk sterile injectable steroid medications were known in Dr. Bhamhani's profession and were knowable to her had she reasonably looked or inquired. Moreover, when Dr. Bhambhani chose to purchase sterile injectable drugs from an out-of-state compounding pharmacy through a means and manner—providing formerly treated patients' names to acquire five 5ml vials per patient—which she knew or had reason to know violated prescription laws, she and the other Box Hill Defendants could reasonably foresee (and should have foreseen) that NECC was not a trustworthy company which could be relied upon to comply with other exacting, critical manufacturing standards and requirements necessary to safely and reliably compound and dispense sterile injectable medications. Box Hill Defendants facilitated Mr. Cadden's criminal conduct and his convictions simply do not exonerate the Box Hill Defendants from their own negligence in choosing NECC as the supplier of steroids for injection into or near their patients' spinal columns.

D. Punitive damages may be legally assessed and are warranted under the facts.

The Court has already ruled Plaintiffs' allegations regarding Box Hill Defendants' conduct are sufficient to support a claim for punitive damages. *See* Dkt. No. 2225 at 7 (September 8, 2015 Memorandum Opinion). Yet, despite this ruling, Defendants ask the Court presently to revisit this and take the issue of punitive damages away from the jury by ruling Plaintiffs' punitive damages claim cannot succeed as a matter of law. *See* Dkt. No. 3458-1. The Court should deny Box Hill's request for partial summary judgment as it essentially is a motion for reconsideration without basis.

Maryland permits punitive damages in order "to punish a party 'whose conduct is characterized by evil motive, intent to injure, *or fraud*[12]. . . ." *Garcia v. Foulger Pratt Development, Inc.*, 854 A.2d 16, 46 (Md. 2003) (emphasis added) (quoting *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633 (Md. 1992)); *see also* Dkt. No. 2225 at 7 (internal quotations and citation omitted). These characteristics are deemed probative of a defendants' malice which a plaintiff must establish to be awarded punitive damages under Maryland law. Using the Dreisch Complaint as an example, Plaintiffs allege in their negligence count that:

> Defendant Healthcare Providers [Box Hill] thereby acted with oppression, **fraud and malice**, toward Plaintiff, Belinda Dreisch, who requests additional damages for the sake of example and for the purpose of punishing Defendant Healthcare Providers for their conduct, in amounts sufficiently large to be an example to others, and to deter these Defendant Healthcare Providers and others from engaging in similar conduct in the future.

Ex. 16 at ¶ 249 (emphasis added). The Court found this sufficient to allege malice. *See* Dkt. No. 2225 at 7.

Going beyond Plaintiffs' pleadings, however, the record evidence here readily supports a jury reasonably finding that Bhambhani and Box Hill acted with malice and award Plaintiffs punitive damages. To begin with, there is Dr. Bhambhani's failure to investigate and scientifically evaluate preservative-free MPA before incorporating it into her practice for routine use. She did

[12] Maryland law's elements of fraud are: (1) a false representation, while (2) either knowing the falsity of the representation or making it with reckless indifference to the truth, in order to (3) defraud the recipient (induce action or inaction or take advantage by deceit or suppression), and the recipient then (4) relies on the misrepresentation, and (5) suffers compensable injury as a result. *Exxon Mobil Corp. v. Albright*, 433 Md. 303, 334, 71 A.3d 30, 49 (2013); *see also Doe v. Doe*, 122 Md. App. 295, 353, 712 A.2d 132, 160 (1998) (acknowledging that the "Maryland Court of Appeals has stated that an action for fraud can stand on an omission when the relationship between the two parties imposes a duty to disclose."); *Mole v. Jutton*, 381 Md. 27, 47, 846 A.2d 1035, 1047 (2004) (observing that a doctor in obtaining consent has a due care duty to disclose pertinent information).

this essentially on blind faith following a chat in 2003-2004 with a colleague who suggested she use it. She admits to never reading any literature on MPA PF's risks. Ex. 15 at 71:21-73:1, 74:13-77:8,79:22-81:10. Her making such a critical decision in such way at that time is nothing short of stunning. It amounts to a total dereliction of her duties and responsibilities as her patients' learned intermediary. Exacerbating this uncaring adoption of a high risk medication was her incorrect, naive belief that the FDA oversaw the safety and efficacy of every medicine, including those made by compounding pharmacies. *Id*. at 87:11-89:25. Added to these shortcoming was her complete disregard for the requirement a patient be individually evaluated to see they had a medical need for a custom medication instead of a manufactured one before prescribing a compounded medication. Individually, each of these shortcomings in her knowledge or care is appalling. But together they made things even worse for Box Hill's patients because they led to Dr. Bhambhani's failure to properly and adequately inform Box Hill patients about the risks and dangers of the steroid medication she was about to inject into them near their spine.

The standard of care required Dr. Bhambhani "inform a patient of material information, or information that a practitioner 'knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure.'" *McQuitty*, 410 Md. at 5, 976 A.2d at 1022 (quoting *Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977)). Plaintiffs' experts opine she breached this duty prior to the infection outbreak in 2012. She never once discussed with her patients the fact that she was administering a steroid medication made by a compounding pharmacy, nor about the risks and benefits of using a compounded and not FDA approved manufactured steroid. Ex. 14 at 190:1-192:15.

Ms. Dreisch testified that she would have wanted to know if the particular steroid used was not FDA approved, and that such knowledge would have made a difference in deciding whether

to follow Dr. Bhambhani's recommended course of treatment. Ex. 28 at 111:20-113:7. Through her total lack of appropriate care or concern for the medication she selected for her patients, Dr. Bhambhani effectively deceived her patients into believing she treated them with a medication subject to the strictest of FDA controls, when, in reality, the patients were treated with a lesser quality pharmaceutical that carried avoidable grave risks.

Box Hill's reliance on *Miller v. Schaefer*, 80 Md. App. 60, 68, 559 A.3d 813 (1988), is misplaced. *Miller* is inapposite because, here, unlike the physician in *Miller*, Dr. Bhambhani violated both Massachusetts and Maryland prescription drug laws and regulations. *See Pagotto v. State*, 127 Md. App. 271, 342, 732 A.2d 920, 957 (1999) (observing that punitive damages, like statutory regulations and the threat of criminal prosecution share, "the common denominator purpose of deterring negligence of 'an extraordinary or outrageous character' that manifests a 'wanton or reckless disregard of human life.'"). Dr. Bhambhani intentionally provided NECC with a list of prior patients' names to order MPA PF in bulk, and then administered the MPA dispensed and labeled with specific patient's names to many different patients. Dr. Bhambhani's outrageous fraudulent conduct gives rise to the level of maliciousness that punitive damages are meant to deter.

Punitive damages are also warranted under Mass. Gen. Laws Ch. 93A. *See Kraft Power Corp. v. Merrill*, 981 N.E.2d 671, 684 (Mass. 2013) (observing that multiple damages authorized by Mass. Gen. Laws Ch. 93A are punitive in nature, and like punitive damages in tort law, are meant to serve the twin goals of punishment and deterrence). Chapter 93A § 9(3) allows an award of punitive damages when the defendant willfully or knowingly violated the statute. *Rhodes v. AIG Domestic Claims, Inc.*, 961 N.E.2d 1067, 1081 (Mass. 2012). As noted above, and further discussed below, Box Hill Defendants willfully violated Massachusetts pharmacy laws and

regulations, which are controlling, when they submitted fraudulent prescription order forms to obtain preservative-free MPA in bulk quantities from NECC. This deliberately deceptive conduct permits a jury to consider awarding of punitive damages in this case.

E. Plaintiffs' Massachusetts Consumer Protection Law claim is valid.[13]

Mass. Gen. Laws Ch. 93A § 9 provides for civil remedies for consumers and states in part:

> Any person, other than a person entitled to bring action under section eleven of this chapter, who has been injured by another person's use or employment of any method, act or practice declared to be unlawful by section two or any rule or regulation issued thereunder or any person whose rights are affected by another person violating the provisions of clause (9) of section three of chapter one hundred and seventy-six D may bring an action in the superior court, or in the housing court as provided in section three of chapter one hundred and eighty-five C whether by way of original complaint, counterclaim, cross-claim or third party action, for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper.

The Box Hill Defendants violated this law by providing fraudulent prescriptions that enabled NECC to evade governing Massachusetts prescription laws. In the face of this controlling statutory provision, however, Box Hill attempts to fit a square peg into a round hole claiming 93A § 11[14]

[13] This Court denied Box Hill Defendants' Rule 12(b)(6) motion to dismiss Plaintiffs' count for violation of the Massachusetts Consumer Protection Statutes. Dkt. No. 2225 at 6-7.

[14] Mass. Gen. Laws Ch. 93A § 11 provides:

> Any person who engages in the **conduct of any trade or commerce and who suffers any loss of money or property, real or personal**, as a result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two or by any rule or regulation issued under paragraph (c) of section two may, as hereinafter provided, bring an action in the superior court, or in the housing court as provided in section three of chapter one hundred and eighty-five C, whether by way of original complaint, counterclaim, cross-claim or third-party action for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper.

applies. Dkt. No. 3459-1 at 6-7. Section 11, however, is only applicable to those engaging in the conduct of trade or commerce that suffer a loss from another also engaging in the conduct of trade or commerce. *Id*. Plaintiffs, the patients, and intended ultimate consumers of the drugs were clearly not engaged in the conduct of trade or commerce at the time Dr. Bhambhani injected them with contaminated MPA. As such, Section 9, not 11, applies to Box Hill Defendants' actions and Plaintiffs' injuries, rendering Box Hill's argument that the requirement for a sale or transaction primarily or substantially in Massachusetts was not met irrelevant. *See Snyder v. Ads Aviation Maint*., 11 Mass. L. Rep. 97, 2000 Mass. Super. LEXIS at *20 (Jan. 10, 2000) (observing that Section 11 applies only to business sales and transactions, while Section 9 applies to consumer plaintiffs).

Plaintiff are clearly persons under the Act. Under Section 9, the term "person" includes "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entity." Mass. Gen. Laws Ch. 93A §1(a). The Supreme Judicial Court of Massachusetts determined that the "1979 amendment substantially broadened the class of persons who could maintain actions" under Section 9, and that plaintiffs injured by any method, act, or practice of a defendant that was unlawful under Mass. Gen. Laws Ch. 93A § 2 are entitled to relief pursuant to Section 9. *Van Dyke v. St. Paul Fire and Marine Ins. Co.*, 448 N.E.2d 357, 360 (Mass. 1983).

Mass. Gen. Laws Ch. 93A § 2 provides "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." 93A § 2(a). Trade and commerce:

Mass. Gen. Laws Ch. 93A § 11 (emphasis added).

> [S]hall include the advertising, the offering for sale, rent or lease, **the sale**, rent lease **or distribution** of any services and **any property**, tangible or intangible, real, personal or mixed, any security as defined in subparagraph (k) of section four hundred and one of chapter one hundred and ten A and any contract of sale of a commodity for future delivery, and any other article, commodity, or thing of value wherever situate, and shall include any trade or commerce directly or indirectly affecting the people of this commonwealth.

Mass. Gen. Laws Ch. 93A § 1(b) (emphasis supplied). While Section 1(b) includes trade or commerce "directly or indirectly affecting the people" of Massachusetts, trade or commerce is notably not limited only to the people of Massachusetts and includes "sales" to all people, including non-residents of Massachusetts. *See id*.

By submitting bogus fraudulent prescription order forms to NECC in order to obtain preservative-free MPA in bulk quantities in violation of Massachusetts controlled substances laws, the Box Hill Defendants committed a deceptive act and practice which contravened governing Massachusetts' regulations, laws, and guidelines set forth to protect consumer safety,[15] thereby violating Ch. 93A §2 as well, which gives rise to a liability under the Consumer Protection Law. Box Hill Defendants harmed plaintiffs thereby by then exposing unknowing consumers (its Maryland patients) to the significant, unnecessary risk of harm, and actual injury, that Massachusetts' pharmacy laws and regulations were adopted to avoid. *See* Ex. 16 at ¶¶ 349-367; *see also* Mass. Gen. Laws Ch. 94C, §§ 19(b), 22(a). Accordingly, because Plaintiffs satisfy the definition of "person" in Mass. Gen. Laws Ch. 93A § 1(a), they are entitled to relief under Section 9.

[15] In 2012, Massachusetts prescription law required compounded prescription medication such as MPA be dispensed by Massachusetts pharmacies only pursuant to patient specific prescriptions and when dispensed labeled with the name of the patient the medication was prescribed for. Mass. Gen. Laws Ch. 94C §§ 19, 21 (2012). Maryland law is essentially the same.

Box Hill Defendants' attempt to avoid Section 9's application falls short. *See* Dkt. No. 3459-1 at 7-10. This Court has personal jurisdiction over Plaintiffs' Massachusetts consumer protection law claim pursuant to Mass. Gen. Laws Ch. 223A § 3. Section 3 provides personal jurisdiction for a cause of action in law over a person transacting any business in Massachusetts and the alleged cause of action arose from that transaction. 223A § 3(a). Box Hill Defendants conducted numerous business transactions with NECC, knew NECC was based in Massachusetts, directed the fraudulent prescription to NECC in Massachusetts, which it faxed to NECC's fax machine in Massachusetts, and this cause of action arises from Box Hill's negligent prescription and purchase of the contaminated MPA NECC dispensed from Massachusetts. *See, e.g.*, *Good Hope Indus., Inc. v. Ryder Scott Co.*, 389 N.E.2d 76, 81 (Mass. 1979) (exercising personal jurisdiction under 223A § 3(a) over a Texas corporation that conducted numerous business transactions with a party whose headquarters were known to be in Massachusetts). Plaintiff therefore asserts sufficient law and facts to support a valid claim under Section 9 and Box Hill Defendants' motion for partial summary judgment on this issue should be denied.

F. Maryland Post-Verdict Procedures Permit Defendants to Request the Court to Reduce a Jury Award for Medical Expenses.

Box Hill Defendants incorrectly claim they are entitled to limit Plaintiffs' recoverable medical expenses to their individual out-of-pocket expenses prior to trial. *See* Dkt. No. 3460-1. Box Hill's argument misstates Maryland law regarding how damages are awarded for medical expenses in a medical malpractice case. As explained below, Maryland has statutory provisions pursuant to which, in post-verdict proceedings, a defendant health care provider may ask the trial court to reduce a jury award of damages for medical expenses by virtue of payments of such expenses by insurers or other third-parties. This, however, is not a matter for summary judgment or a ruling to keep evidence of Plaintiffs' medical expenses away from the jury.

Maryland follows the common law collateral source rule which permits an injured party to recover in tort cases the full amount of his or her damages, regardless of amounts recovered from third-parties, which includes payment of medical expenses by health insurance companies. *See Motor Vehicle Administration v. Seidel,* 326 Md. 237, 253, 604 A.2d 473,481 (1992). As the Court of Appeals of Maryland explained in *Seidel*, the scope of and rationale behind the collateral source rule is as stated in Restatement (Second) of Torts, § 920A (2), comment b (1977):

> *Payments made or benefits conferred by other sources are known as collateral-source benefits. They do not have the effect of reducing the recovery against the defendant*. The injured party's net loss may have been reduced correspondingly, and to the extent that the defendant is required to pay the total amount there may be a double compensation for part of the plaintiff's injury. But it is the position of the law that a benefit that is directed to the injured party should not be shifted so as to become a windfall to the tortfeasor.

Id. 326 Md. at 254, 604 A.2d at 481-82 (emphasis added).

Maryland does not allow collateral source evidence to be introduced during trial and actual or possible recovery of medical expenses from a third-party may not be considered in awarding damages. *Narayen v. Bailey,* 130 Md. App, 458, 747 A. 2d 195 (2000). Introduction of evidence of benefits from a collateral source is permitted only in post-verdict proceedings and, then, reduction in damages awarded in a medical malpractice case is discretionary. *Narayen*, 130 Md. App. at 468-470, 747 A. 2d at 201-202.

In post-verdict proceedings in medical negligence cases, Maryland statutory provisions in CJP § 3-2A-06(f) allow a defendant to introduce evidence that the plaintiff "has been or will be paid, reimbursed, or indemnified to the extent and subject to the limits stated in CJP § 3-2A-05(h) . . . ." CJP § 3-2A-06(f). A defendant may request a reduction in an award of damages in support of a motion for new trial or remittitur, CJP § 3-2A-05(h), and if a new trial is granted, that evidence is admissible and the jury is to be instructed to consider such evidence, pursuant to CJP § 3-2A-

06(f). Lastly, when remittitur or a new trial is granted, this statute eliminates subrogation and reimbursement, except as provided by federal law, for any sum included in a remittitur or awarded in a new trial on damages. *Narayen*, 130 Md. App. at 468-470, 747 A. 2d at 201-202; *see also* CJP § 3-2A-06(f).

Thus, under Maryland law, Box Hill Defendants are not "entitled" to credit for expenses paid for the benefit of Maryland Plaintiffs by insurers or paid to them by other third-party sources. Box Hill's motion for partial summary judgment seeking such a declaration by the Court should be denied.

III. CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that this Court deny the Box Hill Defendants' Consolidated Motion for Summary Judgement.

Respectfully submitted,

/s/ *Patricia J. Kasputys*
Patricia J. Kasputys, Esq. (*Pro Hac Vice)*
Jay D. Miller, Esq. (*Pro Hac Vice)*
Glenn E. Mintzer, Esq. (*Pro Hac Vice)*
Sharon L. Houston, Esq. (*Pro Hac Vice)*
Law Offices of Peter G. Angelos, P.C.
One Charles Center
100 North Charles Street
Baltimore, MD 21201
410-649-2000 (Phone)
410-649-2101 (Fax)
Attorneys for Plaintiffs Armetta, Bowman, Davis, Dreisch, Farthing, Kashi, and Torbeck

/s/ *Michael Coren*
Harry M. Roth, Esq. (*Pro Hac Vice)*
Michael Coren, Esq.
Cohen, Placitella & Roth, PC
Two Commerce Square
2001 Market Street, Suite 2900
Philadelphia, PA 19103
215-567-3500 (Phone)
215-567-6019 (Fax)
Attorneys for Plaintiff Handy

CERTIFICATE OF SERVICE

I, Michael Coren, hereby certify that a copy of the foregoing document, filed through the CM/ECF system will be accessible to those attorneys who are registered with the Court's electronic filing system and Notice of Electronic filing (NEF), including the attorneys representing the defendants in the above-referenced individual cases, and will be sent to these parties by operation of the CM/ECF system.

Dated: October 16, 2017

/s/ *Michael Coren*
Michael Coren